

REMARKS

The Action of April 8, 2008 is incorrect as claims are not being amended.

The Action of August 1, 2007 does not acknowledge as it should the PRELIMINARY AMENDMENT of March 12, 2007.

The rejection of the claims under 35 USC 102 for anticipation by the cited RU 2160058 is traversed on the basis of the bases of the attached AFFIDAVIT/DECLARATION and following remarks. The AFFIDAVIT/DECLARATION establishes with the veracity of non-lawyered language the fact of criticality of the dimensional relations characterizing claim 1 that distinguish it from the cited RU 2160058.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described in a single prior art reference. *MPEP* 2131 (citation omitted).

Against the fact of critical dimensional relations characterizing claim 1, the Action asserts only Fig. 1 of the cited RU 2160058. However,

When the reference does not disclose that the drawings are to scale and is silent as to dimensions, arguments based on measurement of the drawing features are of little value. *MPEP* 2125 (citation omitted).

The device of the cited RU 2160058 provides for automatic atraumatic installation of medical instruments (catheter, electrode, etc.) in the epidural cavity or subdural space of a spinal cord to receive their benefit. However, the stability of the device is insufficient and the operation for its use requires special attention of a surgeon.

The reason for insufficient stability of the device of the cited RU 2160058 is impact interaction of the end of the body cut and the movable stop in the cut. However, the installation of the medical instruments in the epidural cavity immediately after perforation of

the yellow ligament and in the subdural space after perforation of the hard meninx must be quick and controlled. This teaches toward a percussion type mechanism and, thereby, the need for the improvement resulting from the characterizing of claim 1.

The purpose of the invention is a universal device providing for safe introduction of medical instruments in the epidural cavity or subdural space of spinal cord as, well as other cavities and hollow organs, for example, vessels (arteries and veins). Therefore the technical result of the present invention is usability and simplicity of the claimed device and improvement of its contact with tissues and organs of an operated patient.

The cause-and-effect relation of the structural features of the claimed device and the technical result can be iterated: means for preliminary fixation of a medical instrument; a trigger with a depth scale applied onto the body; and the means for delivering a medical instrument comprising telescopic tubes arranged inside the body. One of the tubes is immovably connected to the body and the other is movable, spring-loaded, mounted with its end portion in a body end face guide and has a detent for retaining said medical instrument in a body slot movable in a longitudinal direction and cooperating with the end face of the slot. The trigger is disposed on the body for travel, fixation and interaction with the detent to set a depth of mounting of said medical instruments, provide for automatic nontraumatic introduction of medical instruments (a catheter, an electrode, etc.) in various spaces and hollow organs of a human organism (e.g., the epidural or subdural space of the spinal cord, vessels (arteries, veins), various hollow organs (cavities of large joints, etc.)) to a required depth.

Stability of medical instrument fixation providing for usability and improvement of device operative element contact with tissues of operated patient organs depends on the ratio

of dimensions of those parts which mostly influence the process of medical instrument fixation.

Interaction of device parts with operated patient organs and tissues depends both on the type of tissue in which the instrument is inserted and on the type and dimension of the inserted instrument.

Research conducted on corpses has shown that in the claimed device the smallest portion of the movable tube within the stationary tube should be not less than a halve of the outer diameter of the movable tube, and the distance between the end guide of the body and facing it end of the stationary tube should be from two to twenty five outer diameters of the movable tube. If said ratio is not followed, it would be impossible to have required coaxiality of the movable and stationary tubes and thereby stable movement of the instrument and secure introduction in tissues of various density. If the smallest portion of the movable tube is less than a half of the movable tube outer diameter, the movable tube often moves askew as it was found out for the device of RU 2160058. If the distance between the ends body guide and facing it end of stationary tube is less than two outer diameters of the movable tube, the pulse is not sufficient enough for required penetration in a tissue as it was found out in case of punctures of the back soft tissues. If the distance between the end guide of the body and facing it end of the stationary tube is more that twenty five; outer diameters of the movable tube, the tube also moves askew, and effective operation of an instrument for puncturing various tissues (for punctures at the back, at femoral arteries and knee joints) becomes impossible.

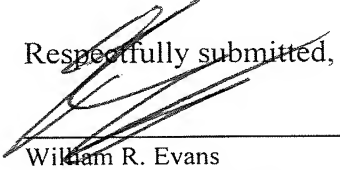
The feature of the means for preliminary fixation of a medical instrument and the medical instrument retention detent adapted to interact with the medical instrument introduced from one and/or the other end of the body provides for usability and reliability of the device.

The simplicity of design including particular embodiments disclosed in dependent claims secure reliability of the claimed device.

Thus, structural features of the claimed device guaranty its medical and technical effectiveness comprising automatic nontraumatic introduction of medical instruments (a catheter, an electrode, etc.) in various spaces and hollow organs of a human organism (e.g., the epidural or subdural space of the spinal cord, vessels (arteries, veins), various hollow organs (cavities of large joints, etc.)) to a required depth.

Reconsideration and allowance are, therefore, requested.

Respectfully submitted,



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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Device for Mounting Medical Instruments

Serial No.: 10/763,294

Group No.:

Filed: January 22, 2004

Examiner:

For: Shkarubo A. N., et al.

In response to Patent Office
dated
(if applicable)

Attorney Docket No.:

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

AFFIDAVIT/DECLARATION TRAVERSING GROUNDS OF REJECTION

I, David Ilich Pitskhelauri, a Russian Federation citizen residing at
(name of declarant)
9/2 Skulev street, apt. 30, Moscow, Russia 109263, declare:
address

That I graduated from Tbilisi State Medical Institute with a degree of B.Sc. in 1985.

That I received a degree of Doctor of Medical Sciences regarding research on
neurosurgery from N.N. Burdenko Research Institute of Neurosurgery, Russian Academy of
Sciences in 2005.

That I have been employed by N.N. Burdenko Research Institute of Neurosurgery,
Russian Academy of Sciences since 1988 and, since 2004, have held and now hold the
position of Leading Researcher.

That I am/am not interested in the above application as an inventor, employee of the
assignee, etc.

That I have read and understood the specification of the above application;

That in order to prove that

I conducted the following experiment:

Research conducted on corpses has shown that in the claimed device the smallest portion of the movable tube within the stationary tube should be not less than a half of the outer diameter of the movable tube, and the distance between the end guide of the body and facing it end of the stationary tube should be from two to twenty five outer diameters of the movable tube. If said ratio is not followed, it would be impossible to have required coaxiality of the movable and stationary tubes and thereby stable movement of the instrument and secure introduction in tissues of various density. If the smallest portion of the movable tube is less than a half of the movable tube outer diameter, the movable tube often moves askew as it was found out for the prototype (patent RU 2160058, Cl. A61B 17/00, 17/34, 2000). If the distance between the end guide of the body and facing it end of the stationary tube is more than twenty five outer diameters of the movable tube, the tube also moves askew, and effective operation of an instrument for puncturing various tissues (for punctures at the back, at femoral arteries and knee joints).

From the above result,

Thus, structural features of the claimed device guaranty its medical and technical effectiveness comprising automatic nontraumatic introduction of medical instruments (a catheter, an electrode, etc.) in various spaces and hollow organs of a human organism: the epidural or subdural space of the spinal cord, vessels (arteries, veins), various hollow organs (cavities of large joints, etc.) to a required depth.

The practice shows that the device is usable, highly reliable and does not require long training of medical personal for its use. The present device can be recommended for use. At present there is no analog of the claimed device in the prior art having such reliable and simple design lightening the work of a surgeon.

That all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: December 20, 2007

Pitskhelauri D.I.

(signature of Declarant)
David Ilich Pitskhelauri
(Doctor of Medical Sciences)

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Alexei Nikolaevich SHKARUBO, et al.

Serial No.: 10/763,294

Group No.: 3767

Filed: January 22, 2004

Examiner: D. Hall

For: DEVICE FOR MOUNTING MEDICAL INSTRUMENTS

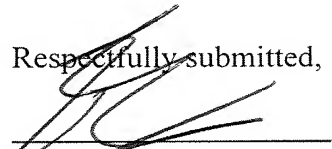
Attorney Docket No.: U 014999-3

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

AFFIDAVIT/DECLARATION

An Affidavit/Declaration is attached.

Respectfully submitted,


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CERTIFICATE OF MAILING/TRANSMISSION (37 CFR 1.8a)

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Date: April 15, 2008

Signature

(type or print name of person certifying)

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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AFFIDAVIT/DECLARATION

Further to my AFFIDAVIT/DECLARATION of December 20, 2007, for the above application, I, David Ilich Pitskhelauri, declare that:

I am not personally related to inventors Shkarubo or Grigoriev named therein nor any others known to me to hold an interest in the application;

I prepared my AFFIDAVIT/DECLARATION of December 20, 2007, because

I was asked to perform a test of the instrument according to the invention and the result turned out to be successful.

And all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statement may jeopardize the validity of the application or any patent issued thereon.

Date: January 22, 2008

Pitskhelauri D. I.
(Signature of Declarant)
David Ilich Pitskhelauri
(Doctor of Medical Sciences)